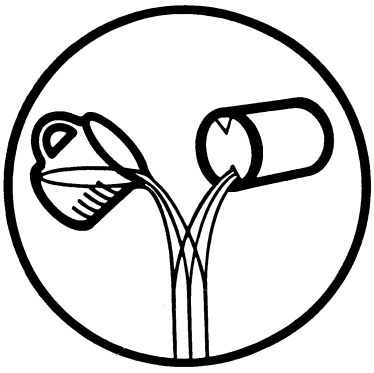

if the addition of water is necessary. The symbol shall be placed on a white background encircled by a dark border.

(e) A warning statement beneath or in close proximity to the ''Directions For Preparation and Use'' that cautions against improper preparation or use of an infant formula, such as ''THE HEALTH OF YOUR INFANT DEPENDS ON CAREFULLY FOLLOWING THE DIRECTIONS FOR PREPARATION AND USE''.

(f) A statement indicating that parents should consult their physicians about the use of infant formulas, such as ''USE AS DIRECTED BY A PHYSICIAN''.

[50 FR 1840, Jan. 14, 1985, as amended at 67 FR 9585, Mar. 4, 2002]

§ 107.30 Exemptions.

When containers of ready-to-feed infant formula, to be sold at the retail level, are contained within a multiunit package, the labels of the individual containers shall contain all of the label information required by section 403 of the Federal Food, Drug, and Cosmetic Act (the act), §§ 107.10 and 107.20, and all appropriate sections of part 101 of this chapter, except that the labels of the individual containers contained within the outer package shall be exempt from compliance with the requirements of section 403 (e)(1) and (i)(2) of the act; and §§ 107.10 (a) and (b)(2) and 107.20 (b), (e), and (f), provided that (a) the multiunit package meets all the requirements of this part; (b) individual containers are securely enclosed within and are not intended to be separated from the retail package under conditions of retail sale; and (c) the label on each individual container includes the statement ''This Unit Not Intended For Individual Sale'' in type size not less than one-sixteenth inch in height. The word ''Retail'' may be used in lieu of or immediately following the word ''Individual'' in the statement.

Subpart C—Exempt Infant Formulas

§ 107.50 Terms and conditions.

(a) *Terms and conditions.* Section 412(f)(1) of the act exempts from the requirements of section 412(a), (b), and (c)(1)(A) of the act infant formulas that are represented and labeled for use by an infant who has an inborn error of metabolism or low brith weight or who otherwise has an unusual medical or dietary problem, if such formulas comply with regulations prescribed by the Secretary. The regulations in this subpart establish the terms and conditions that a manufacturer must meet with respect to such infant formulas.

(b) *Infant formulas generally available at the retail level.* (1) These exempt infant formulas can generally be purchased from retail store shelves that are readily available to the public. Such formulas are also typically represented and labeled for use to provide dietary management for diseases or conditions that are not clinically serious or life-threatening, even though such formulas may also be represented and labeled for use in clinically serious or life-threatening disorders.

(2) Except as provided in paragraphs (b)(4) and (5) of this section, an infant formula manufacturer shall, with respect to each formula covered by this paragraph, comply with the nutrient requirements of section 412(g) of the act or of regulations promulgated under section 412(a)(2) of the act, the quality control procedure requirements of part 106, and the labeling requirements of subpart B of this part.

(3) To retain the exempt status of an infant formula covered by this paragraph, the manufacturer shall submit to the Food and Drug Administration (FDA), at the address specified in paragraph (e)(1) of this section, on or before May 21, 1986, or on or before the 90th day before the first processing of the

infant formula for commercial or charitable distribution, whichever occurs later, the label and other labeling of the infant formula, a complete quantitative formulation for the infant formula, and a detailed description of the medical conditions for which the infant formula is represented. FDA will review the information under paragraph (d) of this section.

(4) To retain the exempt status of an infant formula covered by this paragraph, when any change in ingredients or processes that may result in an adverse impact on levels of nutrients or availability of nutrients is instituted, the manufacturer shall submit to FDA at the address specified in paragraph (e)(1) of this section, before the first processing of the infant formula, the label and other labeling of the infant formula, a complete quantitative formulation for the infant formula, a detailed description of the reformulation and the rationale for the reformulation, a complete description of the change in processing, and a detailed description of the medical conditions for which the infant formula is represented. FDA will review that information under paragraph (d) of this section.

(5) A manufacturer may deviate from the requirements of paragraph (b)(2) of this section only with respect to those specific requirements for which it submits to FDA, at the address specified in paragraph (e)(1) of this section, the medical, nutritional, scientific, or technological rationale (including any appropriate animal or human clinical studies). FDA will review that information under paragraph (d) of this section.

(c) *Infant formulas not generally available at the retail level.* (1) These exempt infant formulas are not generally found on retail shelves for general consumer purchase. Such formulas typically are prescribed by a physician, and must be requested from a pharmacist or are distributed directly to institutions such as hospitals, clinics, and State or Federal agencies. Such formulas are also generally represented and labeled solely to provide dietary management for specific diseases or conditions that are clinically serious or life-threatening and generally are required for prolonged periods of time. Exempt infant formulas distributed directly to institutions such as hospitals, clinics, and State or Federal agencies that are of the same formulation as those generally available at the retail level are subject to the requirements of paragraph (b) of this section rather than to the requirements of this paragraph.

(2) Except as provided for in paragraph (c)(5) of this section, an infant formula manufacturer shall, with respect to each formula covered by this paragraph, comply with the nutrient requirements of section 412(g) of the act or of regulations promulgated under section 412(a)(2) of the act, and the labeling requirements of subpart B of this part.

(3) Each manufacturer of an infant formula covered by this paragraph shall establish quality control procedures designed to ensure that the infant formula meets applicable nutrient requirements of this section, including any special nutritional characteristics for the specific disorders or conditions for which the formula is represented for use. Each manufacturer shall maintain records of such quality control procedures sufficient to permit a public health evaluation of each manufactured batch of infant formula and shall permit any authorized FDA employee at all reasonable times to have access to and to copy and verify the records referred to in this paragraph.

(4) To retain the exempt status of an infant formula covered by this paragraph, the manufacturer shall submit the information required by paragraphs (b)(3) and (4) of this section.

(5) A manufacturer may deviate from the requirements of paragraph (c)(2) of this section only with respect to those specific requirements for which it submits to FDA, at the address specified in paragraph (e)(1) of this section, the medical, nutritional, scientific, or technological rationale (including any appropriate animal or human clinical studies). FDA will review that information under paragaraph (d) of this section.

(6) The requirements of this section do not apply to an infant formula specially and individually prepared for one or more specific infants on a physician's request.

(d) *FDA review of exempt status.* (1) FDA's Center for Food Safety and Applied Nutrition will review information submitted by infant formula manufacturers under paragraph (b) (3), (b) (4), or (c)(4) of this section. On the basis of such review and other information available to the agency, the Center for Food Safety and Applied Nutrition may impose additional conditions on, or modify requirements for, the quality control procedures, nutrient specifications, or labeling of an infant formula, or withdraw a product's exempt status. Such determinations will be made by the Director of the Center for Food Safety and Applied Nutrition.

(2)(i) If after completing its review of all information submitted, the Center for Food Safety and Applied Nutrition concludes that additional or modified quality control, nutrient, or labeling requirements are needed, or that a product's exempt status is withdrawn, the Center for Food Safety and Applied Nutrition will so notify the manufacturer and this notification will specify the reasons therefor. Upon receipt of this notification, the manufacturer has 10 working days to have the decision reviewed under §10.75 by the office of the Commissioner of Food and Drugs. A determination by the Director of the Center for Food Safety and Applied Nutrition that is not appealed becomes a final agency decision.

(ii) After a final decision by the Director or by the office of the Commissioner that a product's exempt status is withdrawn, the manufacturer shall comply with the nutrient requirements of section 412(g) of the act or of regulations promulgated under section 412(a)(2) of the act, the quality control requirements of part 106, and the labeling requirements of subpart B of this part.

(iii) The compliance date for the withdrawal of a product's exempt status or the imposition of additional or modified quality control, nutrient, or labeling requirements is 60 calendar days after issuance of the final decision except as otherwise provided for reasons stated in the decision. If the agency determines that a health hazard may exist and so notifies the manufacturer, withdrawal of a product's exempt status shall be effective on the date of receipt of notification from the Director of the Center for Food Safety and Applied Nutrition. Additional or modified requirements, or the withdrawal of an exemption, apply only to those formulas that are manufactured after the compliance date. A postponement of the compliance date may be granted for good cause.

(3) FDA may decide that withdrawal of an exemption is necessary when, on the basis of its review under paragraph (d)(1) of this section, it concludes that quality control procedures are not adequate to ensure that the formula contains all required nutrients, that deviations in nutrient levels are not supported by generally accepted scientific, nutritional, or medical rationale, or that deviations from subpart B of this part are not necessary to provide appropriate directions for preparation and use of the infant formula, or that additional labeling information is necessary.

(4) FDA will use the following criteria in determining whether deviations from the requirements of this subpart are necessary and will adequately protect the public health:

(i) A deviation from the nutrient requirements of section 412(g) of the act or of regulations promulgated under section 412(a)(2) of the act is necessary to provide an infant formula that is appropriate for the dietary management of a specific disease, disorder, or medical condition;

(ii) For exempt infant formulas subject to paragraph (b) of this section, a deviation from the quality control procedures requirements of part 106 is necessary because of unusal or difficult technological problems in manufacturing the infant formula; and

(iii) A deviation from the labeling requirements of subpart B of this part is necessary because label information, including pictograms and symbols required by those regulations, could lead to inappropriate use of the product.

(e) *Notification requirements.* (1) Information required by paragraphs (b) and (c) of this section shall be submitted to Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

(2) The manufacturer shall promptly notify FDA when the manufacturer has knowledge (as defined in section 412(c)(2) of the act) that reasonably supports the conclusion that an exempt infant formula that has been processed by the manufacturer and that has left an establishment subject to the control of the manufacturer may not provide the nutrients required by paragraph (b) or (c) of this section, or when there is an exempt infant formula that may be otherwise adulterated or misbranded and if so adulterated or misbranded presents a risk of human health. This notification shall be made, by telephone, to the Director of the appropriate FDA district office specified in part 5, subpart M of this chapter. After normal business hours (8 a.m. to 4:30 p.m.), the FDA emergency number, 301–443–1240, shall be used. The manufacturer shall send a followup written confirmation to the Center for Food Safety and Applied Nutrition (HFS–605), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, and to the appropriate FDA district office specified in part 5, subpart M of this chapter.

[50 FR 48187, Nov. 22, 1985, as amended at 61 FR 14479, Apr. 2, 1996; 66 FR 17358, Mar. 30, 2001; 66 FR 56035, Nov. 6, 2001; 67 FR 9585, Mar. 4, 2002; 69 FR 17291, Apr. 2, 2004]

Subpart D—Nutrient Requirements

§ 107.100 Nutrient specifications.

(a) An infant formula shall contain the following nutrients at a level not less than the minimum level specified and not more than the maximum level specified for each 100 kilocalories of the infant formula in the form prepared for consumption as directed on the container:

Nutrients	Unit of measurement	Minimum level	Maximum level
Protein	Grams	1.8	4.5
Fat	do	3.3	6.0
	Percent calories	30	54
Linoleic acid	Milligrams	300	.....
	Percent calories	2.7	.....
Vitamins			
Vitamin A	International Units	250	750
Vitamin D	do	40	100
Vitamin E	do	0.7	.....
Vitamin K	Micrograms	4	.....
Thiamine (vitamin B_1)	do	40	.....
Riboflavin (vitamin B_2)	do	60	.....
Vitamin B_6	do	35	.....
Vitamin B_{12}	do	0.15	.....
Niacin[1]	do	250	.....
Folic acid (folacin)	do	4	.....
Pantothenic acid	do	300	.....
Biotin[2]	do	1.5	.....
Vitamin C (ascorbic acid)	Milligrams	8	.....
Choline[2]	do	7	.....
Inositol[2]	do	4	.....
Minerals			
Calcium	do	60	.....
Phosphorus	do	30	.....
Magnesium	do	6	.....
Iron	do	0.15	3.0
Zinc	do	0.5	.....
Manganese	Micrograms	5	.....
Copper	Micrograms	60	.....
Iodine	do	5	75
Sodium	Milligrams	20	60
Potassium	do	80	200
Chloride	do	55	150

[1] The generic term "niacin" includes niacin (nicotinic acid) and niacinamide (nicotinamide).
[2] Required only for non-milk-based infant formulas.

In addition to the specifications established in the table in this paragraph for vitamins and minerals, the following also apply:

(b) Vitamin E shall be present at a level of at least 0.7 International Unit of vitamin E per gram of linoleic acid.

(c) Any vitamin K added shall be in the form of phylloquinone.

(d) Vitamin B_6 shall be present at a level of at least 15 micrograms of vitamin B_6 for each gram of protein in excess of 1.8 grams of protein per 100 kilocalories of infant formula in the form prepared for consumption as directed on the container.

(e) The ratio of calcium to phosphorus in infant formula in the form prepared for consumption as directed on the container shall be no less than 1.1 and not more than 2.0.

(f) Protein shall be present in an amount not to exceed 4.5 grams per 100 kilocalories regardless of quality, and not less than 1.8 grams per 100 kilocalories of infant formula in the form prepared for consumption as directed on the container when its biological quality is equivalent to or better than that of casein. If the biological quality of the protein is less than that of casein, the minimum amount of